

REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

Request for Continued Examination

Applicants hereby request continued examination of the present application under 37 C.F.R. §1.114.

Claim Amendments

Claim 1 has been amended to recite "injecting" on the same day a composition comprising the virus "into" multiple sites inside the solid tumor. Support for this amendment can be found, for example, in Figure 1B and at page 14, line 6. To be consistent, claim 1 has also been amended to recite that the volume of composition "injected" per site is between about 10% to about 100% of the volume of the tumor. Support for this amendment can be found, for example, at page 5, lines 18-24.

Claims 8-12 have also been amended to be consistent with claim 1.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Rejection Under 35 U.S.C. §102

The rejection of claims 1, 7 and 10-13 under 35 U.S.C. §102 in view of Kooby *et al.* (FASEB Journal 13:1325-1334, 1999) is respectfully traversed for the reasons set forth below.

The standard of anticipation under 35 U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall*, 198 USPQ 344 (CCPA 1978).

Claim 1, as amended, is directed to a method for delivering a virus to a solid tumor to reduce growth of the tumor, comprising administering an effective amount of virus to a subject bearing the tumor, wherein the virus is capable of selectively killing tumor cells, by a base administration of injecting on the same day a composition comprising the virus into multiple sites inside the solid tumor, wherein the volume of the composition injected per site is between about 10% to about 100% of the volume of the tumor (emphasis added). Claims 7 and 10-13 all depend from claim 1, directly or indirectly, and hence recite all the elements of claim 1, including the element of multiple injections into a tumor on the same day.

Kooby et al. teach the use of a herpes virus, G207, in the treatment of human colorectal cancer and liver metastases. Kooby et al. teach a single injection of 50 µl of viral composition into a tumor of 50 mm<sup>3</sup>, but not multiple injections of the viral composition into the tumor on the same day. Accordingly, Kooby et al. do not teach each and every element of the claimed invention, and the requirement of 35 U.S.C. §102 is not met.

Therefore, withdrawal of this rejection is respectfully requested.

#### Rejection Under 35 U.S.C. §103

The rejection of claims 1-6 and 14-21 under 35 U.S.C. §103(a) over Kooby *et al.* (FASEB Journal 13:1325-1334, 1999) in view of Lee *et al.* (WO 99/08692) is respectfully traversed for the reasons set forth below.

To properly issue a rejection under 35 U.S.C. §103, the USPTO bears the initial burden to establish a *prima facie* case of obviousness by meeting three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at the claimed invention. *In re Vaeck*, 20 USPQ 2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference or the combination of references must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974).

Claim 1, as described above, requires the element of multiple injections into the tumor on the same day. Claims 2-6 and 14-21 ultimately depend from claim 1, and hence require this element as well.

Kooby et al. teach the use of a herpes virus, G207, in the treatment of human colorectal cancer and liver metastases. Kooby et al. teach a single injection of 50 µl of viral composition into a tumor of 50 mm<sup>3</sup>, but not multiple injections of the viral composition into the tumor on the same day. Lee et al. teach the use of reovirus in reducing tumor growth, but the reference does not specifically teach or suggest multiple injections of the viral composition into the tumor on the same day. Since neither reference teach or suggest this element, combining the references does not cure the deficiency.

Accordingly, the combination of cited references do not teach or suggest all the claim elements, and the requirement under 35 U.S.C. §103 is not satisfied. Therefore, withdrawal of this rejection is respectfully requested.

### Conclusions

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

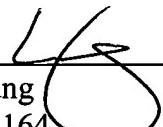
Applicant : Coffey, et al.  
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Attorney's Docket No.: 16596-015001

Enclosed is a \$385 check for the RCE fee required under 37 CFR 1.17(e). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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